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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,949	07/03/2003	Theodosios Korakianitis	716875.6	4629
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Joseph E. Zahner 4 Meredith Drive Sparta, NJ 07871			EXAMINER ALTER, ALYSSA M	
			ART UNIT	PAPER NUMBER
			3762	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/613,949

Applicant(s)

KORAKIANITIS ET AL.

Examiner

ALYSSA M. ALTER

Art Unit

3762

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) ____ is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

DETAILED ACTION

Response to Arguments

Applicant's arguments filed August 22, 2007 have been fully considered but they are not persuasive.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., rare earth bar magnets with annular magnets) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In response to applicant's argument that Kurpanek fails to teach or suggest blood handling, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Although Kurpanek discloses a totally artificial heart, Kurpanek remains capable of handling the blood in a manner similar to the instant invention, according with the pending claims.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

1. Claims 35, 42, 53, 57-58, 60-61 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Specifically, the claiming of structures being in contact with or implanted within the body amounts to an inferential recitation of the body, which renders these claims non-statutory.

For example, the examiner recommends changing the following:

As to claims 35, 42, 53 "such that when the device is deployed in a patient, the device can cause" to –the device is configured to cause--.

As to claim 57, the examiner recommends removing "when deployed in a patient", since it is understood the device will be implanted in a patient.

As to claim 58, the examiner recommends omitting "which, when deployed in the patient can be" and thus leaving the remaining "a L-VAD disposed" and "a R-VAD disposed" to enable positive recitation of statutory subject matter. Furthermore, the examiner recommends removing "when deployed in a patient", since it is understood the device will be implanted in a patient.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 32-61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague and appear to be method

claims since it provides no further structure (i.e., not positively reciting the components), but a mere recitation of intended use for such structure.

As to claim 32, 35, 39, 42, 57, the pump is not positively recited and merely inferentially included, "i.e., further comprising a hydraulic pump for" (similar to claim 53). As a result it is unclear if the Applicant is claiming a hydraulic pump in the system as a means of actuating the magnet or if there is another means for actuating the magnet and the hydraulic pump is merely in communication with the magnet.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 32, 35-36, 39, 42-55 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kurpanek (US 3,974,854). Kurpanek discloses an implantable artificial heart with magnets and a hydraulic pump as depicted in figure B2. Kurpanek discloses the claimed invention except for the annular or open center magnets. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the shape of magnets, since it has been held that the configuration of the claimed element is a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular

Art Unit: 3762

configuration of the claimed element was significant. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) See the MPEP 2144.04. 0

2. Claims 33-34, 37-38, 40-41 and 56-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over the modified Kurpanek (US 3,974,854), as applied to claims 32, 35-36, 39, 42-58 and 61 above. The modified Kurpanek discloses the claimed invention except for the positioning of the device. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the placement of the device as taught by the modified Kurpanek to be disposed between the aortic valve and aortic arch or between the pulmonary valve or the pulmonary trunk since it was known in the art to position a valve replacement system in proximity to the valve in need or replacement to yield the predictable results of compensating for a damaged or diseased heart.

Allowable Subject Matter

1. Claim 60 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALYSSA M. ALTER whose telephone number is (571)272-4939. The examiner can normally be reached on M-F 9am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/
Primary Examiner, Art Unit 3762

/Alyssa M Alter/
Examiner
Art Unit 3762